

**REMARKS**

Claims 1-19 are pending. Claims 7-15, 18, and 19 have been withdrawn from consideration.

Claims 1-7, 12, and 16-19 have been amended.

Claim 1 has been amended to incorporate process limitations from claim 7.

Claims 2 and 4 have been amended to place these claims into independent form and to set forth the spectra from Figures 1 and 2, respectively.

The preambles of claims 3 and 5 have been amended to recite “Atorvastatin calcium Form V.”

Claim 6 has been amended so as to depend from claim 1.

The preamble and step c) of claims 7 and 12 have been amended to recite “atorvastatin calcium Form V.”

Claim 16 has been amended to change its dependency.

Claim 18 has been amended to make claim 18 dependent from claims 2 or 4 and to recite “atorvastatin calcium Form V” in its preamble.

Claim 19 has been amended to make claim 19 dependent from claims 2 or 4 and to recite “or hydrate thereof” in its preamble.

The Applicants thank the Examiner for indicating the claim 17 is allowed over the art of record.

The rejections under 35 U.S.C. §112

Claims 1-6 and 16 were rejected as being indefinite.

Claims 1, 3, 5, and 6 were said to be indefinite because “Atorvastatin calcium Form V” is not defined in the claims. It was said that this rejection could be overcome by adding the X-ray diffraction data and <sup>13</sup>C NMR data to the claims. It was suggested that “Form V” be reinserted into claims 3 and 5. (Office Action, paragraph bridging pages 4 and 5). Claims 2 and 4 were said to be indefinite because they refer to figures (Office Action, page 5, second paragraph).

The Applicants do not agree with these rejections. Claims are not to be read in a vacuum, but instead are to be read in light of the specification. A claim is definite if one skilled in the art would understand the bounds of the claim when read in light of the specification (*Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081 (Fed. Cir. 1986)). As the Office Action points out, there is a clear teaching in the specification at, inter alia, pages 5 and 6, of the characteristics that distinguish Form V from other forms of atorvastatin (see the Office Action, at the bottom of page 4). Thus, one skilled in the art, reading the present claims in light of the specification, would understand their bounds. That is all that is necessary in terms of definiteness.

Nevertheless, in the interest of expediting prosecution, the Applicants have amended the rejected claims as follows, in order to even more particularly point out and distinctly claim the invention.

Claim 1 has been amended to define Form V atorvastatin in product-by-process format, incorporating limitations from claim 7. The Applicants submit that the recitation of the process steps would make it even clearer to one skilled in the art what the bounds of claim 1 are.

Claims 2 and 4 have been amended to include copies of the figures formerly referenced.

Claims 3 and 5 have been amended to re-insert the phrase “Form V,” as suggested in the Office Action, but have not been further amended to recite both X-ray diffraction data and  $^{13}\text{C}$  NMR data. The Applicants submit that the recitation of either X-ray diffraction data, as in claim 3, or  $^{13}\text{C}$  NMR data, as in claim 5, is adequate to impart definiteness to the claimed invention. See the specification, at page 5, lines 13-18, where it is taught that the powder X-ray diffraction pattern of Form V is sufficient to distinguish Form V from other forms of atorvastatin as well as from amorphous atorvastatin. See also the specification, at page 6, lines 19-23, where it is taught that the  $^{13}\text{C}$  NMR spectrum of Form V is sufficient to distinguish Form V from other forms of atorvastatin as well as from amorphous atorvastatin.

As the above quote from Orthokinetics attests, the test for definiteness is whether one skilled in the art would understand the bounds of the claimed subject matter. Further insight into this test for definiteness comes from Application of Mercier, 185 USPQ 774, (CCPA 1975), where the court indicated that claims are definite if one skilled in the art can determine whether particular subject matter is

within the scope of the claims: “[I]f one can determine whether a particular catalytic process for splitting acetals and hemi-acetals is or is not within the scope of a claim, the claim fulfills its purpose as a definition.” The Federal Circuit followed similar reasoning in All Dental Prdx LLC v. Advantage Dental Products, Inc., 64 USPQ2d 1945, 1949 (Fed. Cir., 2002): “The primary purpose of the definiteness requirement is to ensure that the claims are written in such a way that they give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public, e.g., competitors of the patent owner, can determine whether or not they infringe.”

There can be no doubt that one skilled in the art can easily determine if a particular crystalline form of atorvastatin is within the scope of claims 3 and 5. One skilled in the art would simply obtain X-ray diffraction data or  $^{13}\text{C}$  NMR data for that crystalline form and compare such data to the X-ray data limitations recited in claim 3 or the  $^{13}\text{C}$  NMR data recited in claim 5. Thus, under the tests specified in Mercier and All Dental Prdx, these claims are definite.

Claim 6 has been amended to depend from claim 1.

Claim 16 has not been amended in view of the amendments to claim 1, from which claim 16 depends.

In view of the above, it is respectfully requested that these rejections be withdrawn.

Rejoinder of claims


It is believed that present claims 1-6, 16, and 17 are in form for allowance. Accordingly, it is respectfully requested that claims 7-15, 18, and 19 be rejoined with claims 1-6, 16, and 17 since claims 7-15, 18, and 19 depend from claims 1-6, 16, and 17.

The time for responding to the Office Action was set for August 19, 2004. Therefore, it is believed that this Response is timely and that no fee is required for extension of time. If this is in error, please treat this paper as including a Petition for the Extension of Time under 37 C.F.R. § 1.136(a) for a period sufficient to permit the filing of a response and charge the required fee to Kenyon & Kenyon's Deposit Account No. 11-0600.

The Applicants hereby also make a Conditional Petition for any relief available to correct any defect seen in connection with this filing, or any defect seen to be remaining in this application after this filing. The Commissioner is authorized to charge Kenyon & Kenyon's Deposit Account No. 11-0600 for any fees associated with such Conditional Petition.

Respectfully submitted,

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